



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0257]

Summit on Color in Medical Imaging; Cosponsored Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of cosponsored public workshop; request for comments.

Summary: The Food and Drug Administration (FDA) and cosponsor International Color Consortium (ICC) are announcing the following public workshop entitled “Summit on Color in Medical Imaging: An International Workshop on the Technical Framework for Consistency and Interoperability Approaches for Dealing with Color in Medical Images.” The purpose of the workshop is to bring together key stakeholders to clearly identify areas of need, investigate solutions, and propose best-practice approaches. The recommendations of the summit might include the creation of a technical special interest group either as part of the ICC or in some other forum and the establishment of best-practice guidelines for industry.

Date and Time: The workshop will be held on May 8 and 9, 2013, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Contact: Aldo Badano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 3116, Silver Spring, MD 20993-0002, 301-796-2534, Aldo.Badano@fda.hhs.gov.

Registration: Registration is free and on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. on April 26, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

To register for the public workshop, please visit FDA's Medical Devices News & Events-Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, mailing address, email address, and telephone number. Those without Internet access should contact Susan Monahan at 301-796-5661 to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

If you need special accommodations due to a disability, please contact Susan Monahan (Susan.Monahan@fda.hhs.gov or 301-796-5661) no later than April 26, 2013.

Streaming Webcast of the Public Workshop: This workshop will also be available via Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. on April 26, 2013. Early registration is recommended because Webcast connections are limited.

Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after May 2, 2013. If you have never attended a Connect Pro event before, test your connection at

https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview.

(FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Requests for Oral Presentations: This workshop includes a public comment session. If you wish to present during a public comment session, you must indicate this at the time of registration. You shall also submit a title and short abstract of your comments to Veronika Lovell at Veronika.lovell@sunchemical.com.

Comments: FDA is holding this public workshop to obtain information on the topics identified in Section II. No commercial or promotional material will be permitted to be presented or distributed at the workshop. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is May 31, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the

heading of this document. In addition, when responding to specific topics as outlined in section II, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

There is increased utilization of color in several areas of medical imaging and a wider range of availability of a variety of hardware and software platforms that rely on medical and non-medical devices to implement medical imaging product solutions for color imagery. This new reality has brought up issues related to the interoperability of devices and to the framework of accurately dealing with color data in medical imaging products. This workshop brings together key stakeholders to clearly identify areas of need, investigate solutions and propose best-practice approaches. The recommendations of the summit might include the creation of a technical special interest group either as part of the ICC or in some other forum and the

establishment of best-practice guidelines for industry. The summit will address emerging utilization of color in medical imaging in areas including clinical photography, ophthalmic photography, digital microscopy, digital histopathology, endoscopy, laparoscopy, telemedicine, handheld mobile displays, display devices, color measurement, and standards and professional group recommendations from organizations such as the Digital Imaging and Communications in Medicine, ICC, International Commission on Illumination, International Electrotechnical Commission, and American Association of Physicists in Medicine.

II. Topics

There is increasing use of color in medical imaging but so far there is no clear definition of a technical framework for color management across the imaging chain from acquisition, pre- and post-processing, to storage, transfer and display. Due to the increasing use of color images and the need for integrated electronic health records, this issue is of current relevance for device manufacturers, users, and regulators. In addition, topics might include color methods for handheld display devices, system approaches for color consistency, and inter-vendor interoperability.

Scheduled session topics include: (1) General landscape of color use in medical imaging, (2) whole-slide imagers and digital microscopy/histopathology, (3) endoscopy and laparoscopy, (4) other medical imaging modalities, (5) standards and professional organization recommendations, (6) color in telemedicine, and (7) color in mobile displays.

Dated: March 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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